

59470

May 27, 1998

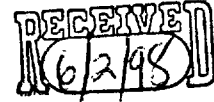
Office of Special Nutrition (HFS-450)

Center for Food Safety and Applied Nutrition 35 '98 JUN -5 A9:23

Food and Drug Administration

200 C Street, S.W.

Washington, DC 20204



RE: Statements of Nutritional Support – Notification

Dear Sir/Madam:

This letter is submitted by New Vision International, Inc. ("New Vision"), 1920 East Broadway, Tempe Arizona 85282, to notify the agency that pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), statements of nutritional support are being made for dietary ingredients contained in dietary supplements marketed by New Vision as follows:

1. FlexRite™

new vision
international

- FlexRite™ is a proprietary blend of incredible Glucosamine sulfate, MSM (methylsulfonylmethane), Boswellia extract, and other ingredients that nutritionally support and promote joint function and help your body naturally build connective tissue.
- Glucosamine sulfate is naturally produced within your body to manufacture connective tissue.
- At the same time, it helps generate the viscous fluid that lubricates joints.
- Glucosamine sulfate helps generate the viscous (synovial) fluid that lubricates joints.
- An essential trace mineral, Manganese is required for both collagen and chondroitin sulfate synthesis.
- Vitamin C is important for the synthesis of the two primary components of connective tissue: collagen and glycosaminoglycan.
- FlexRite™ is the easy, effective way to provide the nutritional support for healthy joint function.
- Nutritionally supports and promotes joint function.
- Today, your customers can give all the joints in their bodies the nutritional support they need with FlexRite™.
- Helps the body naturally build connective tissue.
- Manganese is required for both collagen and chondroitin sulfate synthesis.

• 1920 East Broadway
Tempe, AZ 85282-1702
T.602-303-5999
F.602-303-5901

Teamwork.
Integrity.
Freedom.

97S - 0162

LET 1678

Office of Special Nutrition (HFS-450)
May 27, 1998
Page 2

The disclaimer required by FFDCA § 403(r)(6)(C) accompanies each statement of nutritional support.

The undersigned certifies that the information contained in this notice is complete and accurate, and that New vision has substantiation that each statement of nutritional support is truthful and not misleading.

Very truly yours,

A handwritten signature in black ink, reading "James B. Roufs". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James B. Roufs
Vice President
Research & Development

JBR/pb
L:/Legal/StructureFunction